MAY 18 2012

# 510(K) SUMMARY

## Double Lumen Video Tracheoscope (DLVT™) System

## 510(k) Number K113576

**Applicant's Name:** ETView Ltd.
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Israel
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**Contact Person:** Yoram Levy, Qsite
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Binyamina, Israel 30500
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**Trade Name:** ***Double Lumen Video Tracheoscope (DLVT™) System***

**Device Type:** Endobronchial tube (EBT)

**Preparation Date:** November 23, 2011

**Classification:** **Regulatory Name:** Tracheal/bronchial differential ventilation tube

**Product Code:** CBI
**Regulation No:** 21 CFR 868.5740
**Class:** II
**Classification Panel:** Anesthesiology

**Device Description:**

The ETView ***Double Lumen Video Tracheoscope (DLVT™) System*** functions as a standard 37 French size endobronchial tube that additionally has an embedded video imaging device in its tracheal lumen. The system provides a video image of the patient's

bronchus, which is displayed on the monitor, for as long as the DLVT™ is inside the patient's bronchus.

Visualization of the bronchus is used to verify placement and repositioning of the endobronchial tube during the intubation procedure or throughout surgery.

The device is indicated for non-MRI environment only.

**Intended Use Statement:**

The ETView ***Double Lumen Video Tracheoscope (DLVT$^{TM}$)*** is intended to isolate the left or right lung of a patient for intensive care or surgery, one lung ventilation or one lung anesthesia.

The ***DLVT$^{TM}$ System*** is indicated for verifying tube placement and repositioning.

**Predicate Devices**: Substantial equivalence to the following predicate devices is claimed:

| Device Name | 510k No | Date of Clearance |
|---|---|---|
| **ETView Tracheoscopic Ventilation Tube (TVT$^{TM}$)** | K082420 | October 8, 2008 |
| **Well LEAD Endobronchial Tubes** | K092886 | March 11, 2010 |

**Performance Standards**

***Double Lumen Video Tracheoscope (DLVT$^{TM}$)*** was tested and complies with the following standards:

- ISO 5361:1999 Anaesthetic and respiratory equipment -- Tracheal tubes and connectors
- ISO 16628:2008 Tracheobronchial Tubes – Sizing and marking
- ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide
- AAMI TIR28:2001 Product adoption and process equivalency for ethylene oxide sterilization
- ISO 14971-1:2007 Risk management for medical devices

- ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing

A detailed description appears in **Section 14**.

**Performance Testing**

Performance testing demonstrated that the ***Double Lumen Video Tracheoscope (DLVT™)*** is as safe and effective as the cleared predicate devices.

The following performance tests were conducted:

- Determination of Cuff Resting Diameter
- Cuff Leak Resistance Integrity
- Resistance to Cuff Herniation
- Cuff Symmetry
- Resistance to tube collapse
- Air Flow Resistance
- Thermal Safety
- Determination of effective inside diameter
- Tracheal Seal
- Determination of the bronchial segment
- Cadaver Test
- MR Environment Non-Clinical Test

**Comparison to the Predicate Devices**

The intended use of the DLVT™ is similar to the intended use of Well LEAD Endobronchial Tubes, previously cleared under K092886. The indication for use of the DLVT™ system is similar to the indication of ETView Tracheoscopic Ventilation Tube (TVT™), previously cleared under K082420.

Both the DLVT™ and the TVT™ systems integrate imaging and lighting components into the wall of a tube for patient ventilation. The structure, the material, the dimensions and the sterilization method of the DLVT™ are similar to the cleared Well LEAD Endobronchial Tubes. The light source, the imaging sensor, the video transfer and format, the display and the power supply of the DLVT™ System are identical to the cleared ETView TVT™.

The minor differences between the DLVT™ System and its predicate devices do not raise any new questions of safety or efficacy. Moreover, performance testing demonstrated that the DLVT™ is as safe and effective as the predicate devices. Thus, the DLVT™ System is substantially equivalent to Well LEAD Endobronchial Tubes and ETView TVT™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 18 2012

ETView Ltd.
C/O Mr. Yoram Levy
Qsite
31 Haavoda Street
Binyamina
ISREAL 30500

Re: K113576
Trade/Device Name: Double Lumen Video Tracheoscope (DLVT™) System
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: II
Product Code: CBI
Dated: April 19, 2012
Received: April 24, 2012

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

**510(k) Number (if known):**

**Device Name:** ***Double Lumen Video Tracheoscope (DLVT™) System***

**Indications for Use:** The ETView ***Double Lumen Video Tracheoscope (DLVT™)*** is intended to isolate the left or right lung of a patient for intensive care or surgery, one lung ventilation or one lung anesthesia.
The ***DLVT™ System*** is indicated for verifying tube placement and repositioning.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
510(k) Number

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 113576